

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
28 December 2000 (28.12.2000)

PCT

(10) International Publication Number
WO 00/78382 A1

(51) International Patent Classification⁷: A61M 16/06

(21) International Application Number: PCT/AU00/00677

(22) International Filing Date: 16 June 2000 (16.06.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

PQ 1040	18 June 1999 (18.06.1999)	AU
1916/99	18 June 1999 (18.06.1999)	AU
29/115,618	16 December 1999 (16.12.1999)	US
09/504,234	15 February 2000 (15.02.2000)	US

(71) Applicant (for all designated States except US): RESMED LTD. [AU/AU]; 97 Waterloo Road, North Ryde, NSW 2113 (AU).

(72) Inventors; and

(75) Inventors/Applicants (for US only): GUNARATNAM, Michael, Kassipillai [AU/AU]; 3 Keiley Street, Marsfield, NSW 2122 (AU). AMARASINGHE, Amal, Shirley [AU/AU]; 604 Pennant Hills Road, West Pennant Hills, NSW 2125 (AU).

(74) Agents: DAVIDSON, Geoffrey, Robert et al.; Halford & Co., Level 7, 1 Market Street, Sydney, NSW 2000 (AU).

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

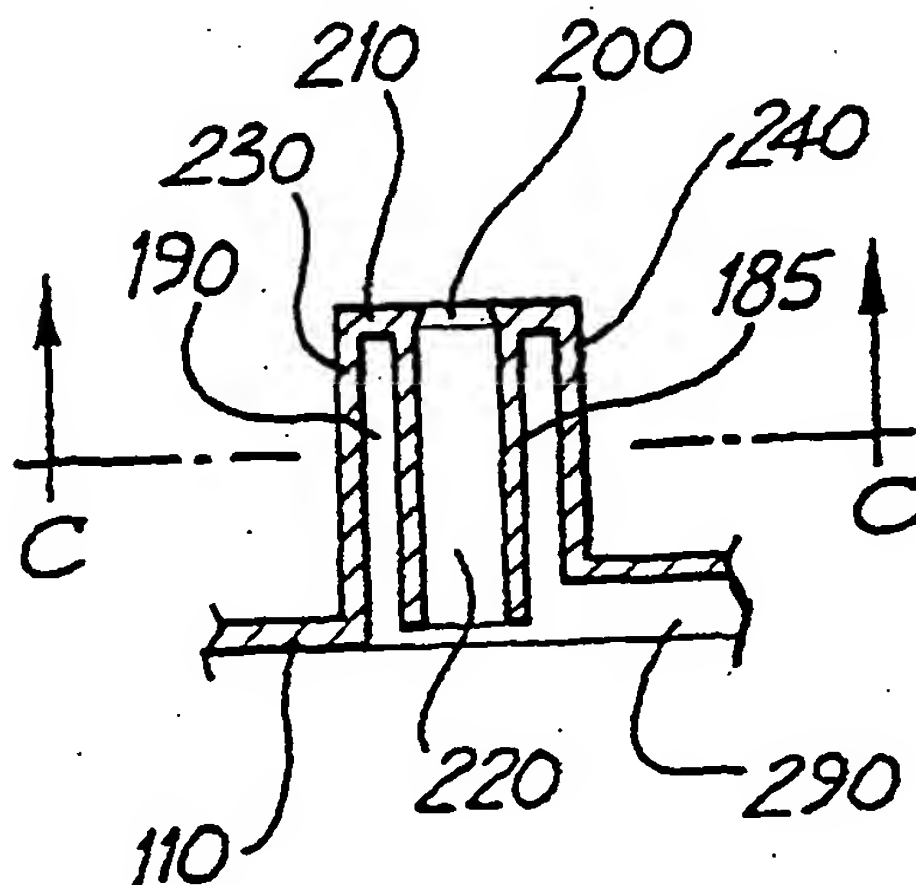
(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:

— With international search report.

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: MASK PORTS



(57) Abstract: Mask ports (180) for attaching supplemental oxygen tubes (510) or measurement devices to a respiratory mask are downwardly directed and recessed into the base (110) of the mask frame (100). The ports may comprise a pair of downwardly extending tubular spigots (185) each housed in a respective recess (190) in the base (110), with a shallow bridging recess (290) therebetween for receiving a bridging piece (300) of a closure cap (280).

WO 00/78382 A1

Mask Ports

Field of the Invention

- 5 The invention relates to masks suitable for the delivery of breathable gases to a patient for the treatment of sleep disordered breathing (SDB), and to mask ports for such masks.

Background of the Invention

10

Respiratory masks used in the treatment of SDB may comprise a nasal mask, designed to fit over a patient's nose, or a full face mask designed to fit over the nose and mouth of the patient. In both cases, the mask is held in position by headgear.

- 15 The mask generally comprises a relatively rigid shell, termed a frame, which defines a rearwardly opening cavity covering the patient's nose and/or mouth and a soft portion, termed a cushion, which spaces the frame away from the face for comfortable contact.

- 20 The air or other breathable gas is supplied by a blower and passed along a flexible conduit to the mask. The conduit is typically of relatively large bore, for example approximately 2cm diameter, with the mask frame having a gas inlet of comparable diameter.

- 25 In addition to the gas inlet, the mask may also have CO₂ washout vents and one or more small diameter ports through which supplemental oxygen may be introduced or measurements made. The ports typically comprise a pair of cylindrical connectors moulded into the mask frame, usually projecting forward from the front surface of the frame. The mask ports typically also include a cap which prevents leakage of air from the mask when the port is not in use.

30

Depending on the part construction and the relative diameters of the port and the tubing which supplies supplemental oxygen, the port may function as a male or a female connector.

- 5 The Mirage® nasal mask (ResMed Ltd.) is a generally triangular mask with a gas inlet tube extending upwards from its apex. The two ports of that mask are located in the front of the gas inlet tube just above the patient's eye level, between a pair of shield projections. A single cap of silicone rubber covers both ports, and has tabs at either end to facilitate removal by pulling on the tabs in a direction away from patient's face.

10

There is a need for ports which are conveniently located on the mask, which are protected from accidental breakage and which do not foul tubing. There is a need for a corresponding port cap which is sufficiently large so as to be easy to handle and which is not so small as to be easily lost.

15

Summary of the Invention

- The present invention provides a mask frame for a respiratory mask, said mask frame defining a mask cavity adapted for communication with a patient's airways and including a gas inlet adapted for connection to a supply of breathable gas, further including a recess in a lower portion of the mask frame, at least one mask port comprising a downwardly extending tubular spigot located in said recess, said spigot having a bore communicating with the mask cavity via a port aperture in the mask frame.

25

The cap is preferably constructed from a single piece of silicone or other elastomeric material with tabs preferably to the front of the mask when positioned on the ports. Preferably the base of the cap is flush with the base of the mask. Preferably, to remove the cap, the tabs are pulled in a downwards motion, relative to the front of the mask.

30

A further form of the invention provides a mask frame for a respiratory mask, said mask frame defining a mask cavity adapted for communication with a patient's

airways including a gas inlet adapted for connection to a supply of breathable gas, further including at least one downwardly opening port located in a lower portion of the mask frame and communicating with the mask cavity.

5 **Brief Description of the Drawings**

Further embodiments of the invention will now be described with reference to the accompanying drawings, in which:

10 Fig. 1 shows a side perspective view of a mask frame.

Fig. 2 shows a front view of the mask frame of Fig. 1.

Fig. 3a shows a bottom view of the mask frame of Fig. 1.

15 Fig. 3b shows a section B-B from Fig. 3a.

Fig. 3c shows a section C-C from Fig. 3a.

Fig. 4a shows a perspective view of the port cap.

Fig. 4b shows an end view of the port cap.

20 Fig. 4c shows a top view of the port cap.

Fig. 4d shows a front view of the port cap.

Fig. 4e shows a bottom view of the port cap.

Fig. 4f shows a rear view of the port cap.

25 In Figs. 4a to 4f approximate dimensions are indicated in mm.

Figs. 5a to 5c schematically illustrate an alternative embodiment of the invention.

Detailed Description of the Invention

30

Figs. 1 and 2 illustrate a mask frame 100 for a nasal mask, formed as a moulded shell of polycarbonate or similar rigid material, which acts as a body onto which the other

components of the mask are attached. A suitable material for the mask frame is Makrolon 2458 polycarbonate from Bayer.

5 The frame 100 is generally triangular in front view, having a base 110, a pair of inclined side walls 120 extending towards an apex and a front wall 130. The frame defines a mask cavity covering the patient's nose, and is open at its rear. A rim 140 at the rear edge of the base 110 and side walls 120 approximates the contours of the patient's face and is adapted for attachment of a soft mask cushion (not shown) to space the frame away from the patient's face for sealing and comfort. The apex of the
10 frame has an extension 150 for attachment of a forehead support (not shown).

In the illustrated mask frame, a gas inlet aperture 160 is formed in the front wall 130, for connection of a gas supply conduit or similar, which may include an elbow connector (not shown) pivotably connected to the frame. In other forms of mask, the
15 gas inlet aperture may be formed at the apex of the frame.

The mask frame further includes lower headgear connection points 170 for attachment to the headgear which holds the mask in place on the patient's face. Upper headgear connection points may be formed in the forehead support (not shown).

20 With reference to Figs. 1 to 3a, it can be seen that the mask frame includes two ports 180, approximately 2.5 cm apart, located in recesses 190 in the base of the mask frame 100. These recesses are positioned in between the lower headgear strap connection points 170. The ports are positioned so that in use, oxygen or other breathable gas can
25 be delivered close to the patient's nares.

Each port is formed as a tubular spigot 185 with an approximate external diameter of 4mm and an approximate length of 1 cm. The spigot 185 forms the male connector onto which small bore tubing supplying, for example, oxygen, may be attached.

30 An elevational cross-section through the port is shown in Fig. 3b, and a lateral cross-section at Fig. 3c.

As best seen in Figs. 3b and 3c, each recess 190 is approximately rectangular in elevation (Fig. 3a) and closed off from the mask cavity except for an aperture 200 extending through the recess upper wall 210 between the bore 220 of the spigot 185 and the mask cavity. The recess is bounded by the upper wall 210, side wall portions 230, 240 and a rear wall portion 250, and is open at its bottom end. A front wall 260 is formed as a continuation of the front wall 130 of the mask frame. The rear wall portion 250 and one or both side wall portions 230, 240 may be formed as a continuous curve.

These boundary walls 230, 240, 250, 260 of the recess are spaced from the spigot by a sufficient distance, for example at least 1mm, to allow a small bore oxygen tube to be pushed onto the spigot, and also to allow the closure portion 270 of a cap 280 (Figs. 4a to 4f) to be retained.

The base 110 of the mask also includes a shallow bridging recess 290 for receiving the bridge piece 300 joining the two closures 270 of the cap 280.

The bottom edge of the frame front wall 130 includes a pair of small notches 310 through which gripping tabs 320 of the cap extend, so that the tabs extend forward of the front wall for gripping by the user. Pulling downwards on the tab will remove the respective closures 270 from its spigot 185 to allow attachment of an oxygen tube or a tube leading to a measurement device.

The cap 280 is suitably formed of a relatively soft elastomeric material, such as Dow Silastic 94-595 HC silicone.

As can be seen in Figs. 1 and 2, the above construction results in the bottom of the cap 280 being substantially flush with the base 110 of the frame 100, providing a compact and aesthetically pleasing arrangement.

The asymmetric shape of the recessed chamber and corresponding shape of the cap 280 reduces the likelihood that the cap 280 will be incorrectly positioned back-to-front.

- 5 A further advantage of recessing the ports into the mask frame is that the dead volume of the frame is reduced. A further advantage of providing access from the bottom of the mask frame is that the likelihood of fouling the gas delivery conduit is reduced where a swivel connection is used to provide air from the flow generator.
- 10 Another advantage is that the loss of supplemental oxygen through the vent is reduced by positioning the port away from the main vent path.

In other embodiments, there may be one port, or there may be more than two ports. Furthermore, ports may have individual caps. Ports may be connected by way of a
15 small bore tubing or in any other suitable manner to a manometer for measuring pressure in the mask cavity during the setting up of the device or during treatment of SDB. Alternatively, one or more ports may be used in conjunction with transducers and control algorithms to control the operation of an automatically adjusting device.

- 20 In an alternative embodiment, a larger diameter cylinder is used for the port, hence the cylinder will function as a female connector with respect to the supplemental oxygen tubing.

In another embodiment, the spigots could extend within the mask frame to bring the
25 oxygen supply closer to the nares.

Figs. 5a to 5c are schematic front elevational cross-sections of an alternative mask port arrangement 500 with, respectively, an oxygen delivery tube 510 being inserted into a port 520 (Fig. 5a), the delivery tube in position in the port (Fig. 5b), and the
30 tube removed and a cap 530 inserted (Fig. 5c).

The position and orientation of the ports 520 is generally similar to that described above with reference to Figs. 1 to 3c except that the ports 520 are formed as tubes extending upwards into the mask cavity, and open at their upper ends. In common with the previously described embodiment, the base 540 of the mask frame includes a pair of these recessed mask ports, joined by a shallow bridging recess 550.

As can be seen from Figs. 5a and 5b, the port 520 acts as a female connector for insertion from below of a corresponding oxygen supply tube 510 having a diameter chosen for substantially sealing engagement in the port.

10

As shown in Fig. 5c, the configuration of the cap 530 is generally similar to that of Figs. 4a to 4f, including a pair of closure portions 560 joined by a bridging portion 570, except that the closure portions for sealing the ports when not in use are preferably formed as solid plugs rather than as cup-shaped closures as in Figs. 4a to 4f.

15

In another embodiment, the tabs 320 of the cap 280 are below the mask, rather than in front.

20

Although the invention has been described with reference to particular embodiments, it is to be understood that these embodiments are merely illustrative of the application of the principles of the invention. Numerous modifications may be made in the illustrative embodiments of the invention and other arrangements may be devised without departing from the spirit and scope of the invention.

CLAIMS:

1. A mask frame for a respiratory mask, said mask frame defining a mask cavity adapted for communication with a patient's airways and including a gas inlet adapted for connection to a supply of breathable gas, further including a recess in a lower portion of the mask frame, at least one mask port comprising a downwardly extending tubular spigot located in said recess, said spigot having a bore communicating with the mask cavity via a port aperture in the mask frame.
2. A mask frame according to claim 1 wherein said recess is bounded by at least an upper wall portion, opposed side wall portions and a rear wall portion and is open at a bottom end thereof, said wall portions being spaced from the spigot so as to allow a tube to be pushed over the spigot through said open bottom end of the recess.
3. A mask frame according to claim 2 wherein said recess is further bounded by a front wall formed as part of a front wall of the mask frame.
4. A mask frame according to claim 2 wherein said port aperture extends through said recess upper wall.
5. A mask frame according to claim 1, said mask frame being generally triangular in front view and having a front wall, a base, an apex, a pair of inclined side walls extending from respective opposed ends of the base to said apex, wherein said recess is formed in said base.
6. A mask frame according to claim 5 wherein said base includes a pair of said recesses each housing a respective one of said mask ports.
7. A mask frame according to claim 6 further including a removable port cap having a pair of closure portions each adapted to be pushed into a respective one of said recesses to seal a respective one of said ports, and a bridge portion connecting said closure portions.

8. A mask frame according to claim 7 wherein said port cap further includes at least one gripping tab which extends, in use, forward of said front wall of the mask frame.

5

9. A mask frame according to claim 7 wherein, in use, a base of said port cap is substantially flush with said base of the mask frame.

10. A mask frame according to claim 7 wherein said base further includes a shallow bridging recess extending between said pair of recesses, for receiving said bridge portion of the port cap.

11. A mask frame according to claim 2 wherein said gas inlet is located in said front wall of the mask frame, above said at least one recess.

15

12. A mask frame according to claim 1 wherein said mask is a nasal mask, and wherein said at least one port is adapted to introduce oxygen to a position below the patient's nares.

20 13. A mask frame according to claim 1 further including an oxygen delivery tube having an end adapted for insertion in said recess such that an inner surface of said tube substantially seals against an outer surface of said spigot.

25 14. A mask frame according to claim 1 further including an oxygen delivery tube having an end adapted for insertion in said recess such that an outer surface of said tube substantially seals against an inner surface of said spigot.

30 15. A mask frame for a respiratory mask, said mask frame defining a mask cavity adapted for communication with a patient's airways including a gas inlet adapted for connection to a supply of breathable gas, further including at least one downwardly opening port located in a lower portion of the mask frame and communicating with the mask cavity.

16. A mask frame according to claim 15 wherein said port is formed as a tube extending into said mask cavity.
- 5 17. A mask frame according to claim 15, said mask frame being generally triangular in front view and having a front wall, a base, an apex, a pair of inclined side walls extending from respective opposed ends of the base to said apex, wherein said port is formed in said base.
- 10 18. A mask frame assembly according to claim 16 wherein said base includes a pair of said ports.
19. A mask frame according to claim 18 further including a removable port cap having a pair of closure portions each adapted to seal a respective one of said ports,
15 and a bridge portion connecting said closure portions.
20. A mask frame according to claim 19 wherein said port cap further includes at least one gripping tab which extends, in use, forward of said front wall of the mask frame.
- 20 21. A mask frame according to claim 19 wherein, in use, a base of said port cap is substantially flush with said base of the mask frame.
22. A mask frame according to claim 19 wherein said base further includes a
25 shallow bridging recess extending between said pair of recesses, for receiving said bridge portion of the port cap.
23. A mask frame according to claim 15 further comprising an oxygen delivery tube adapted for insertion in said port such that an outer surface of said tube
30 substantially seals against an inner surface of said port.

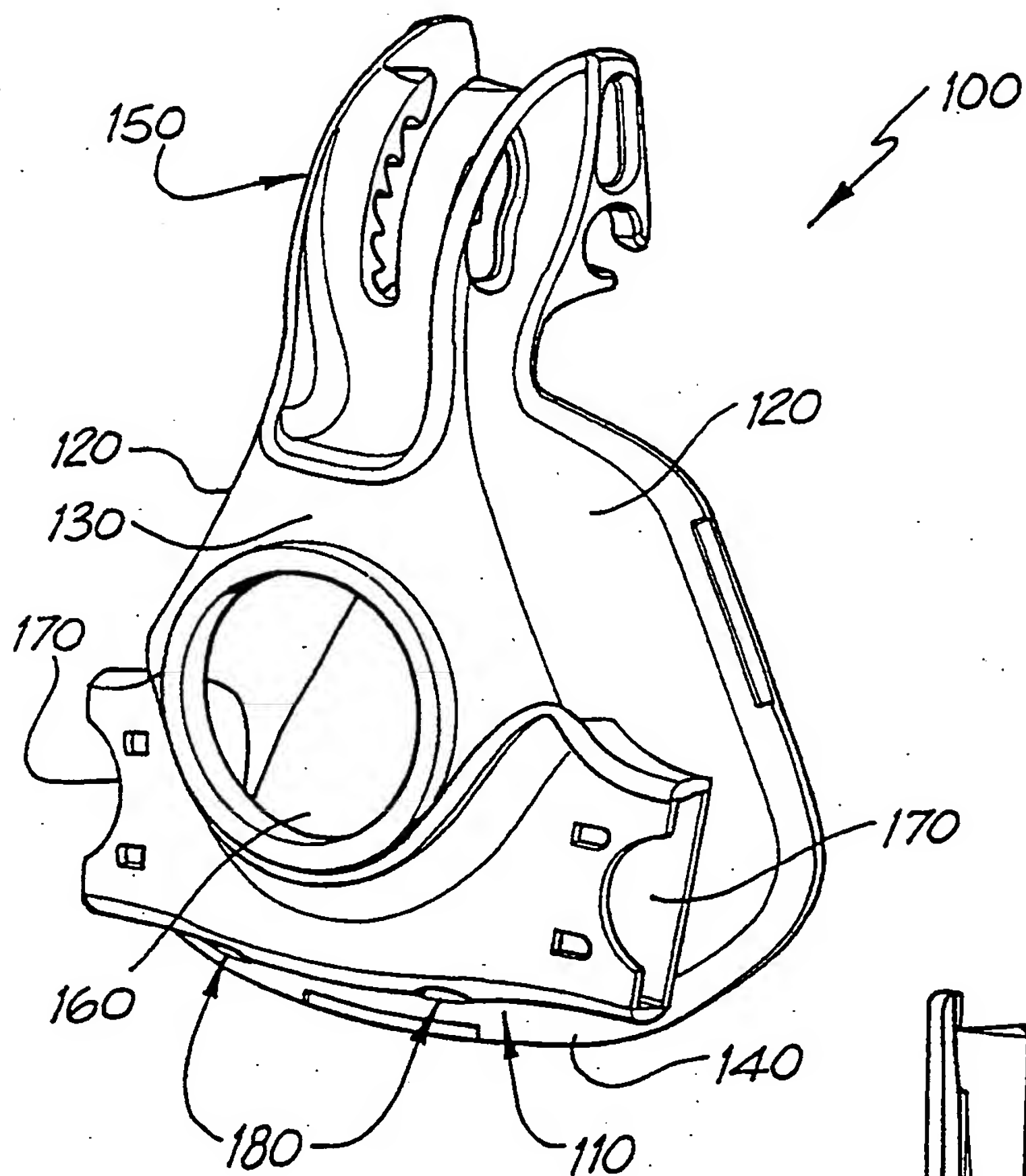


FIG. 1

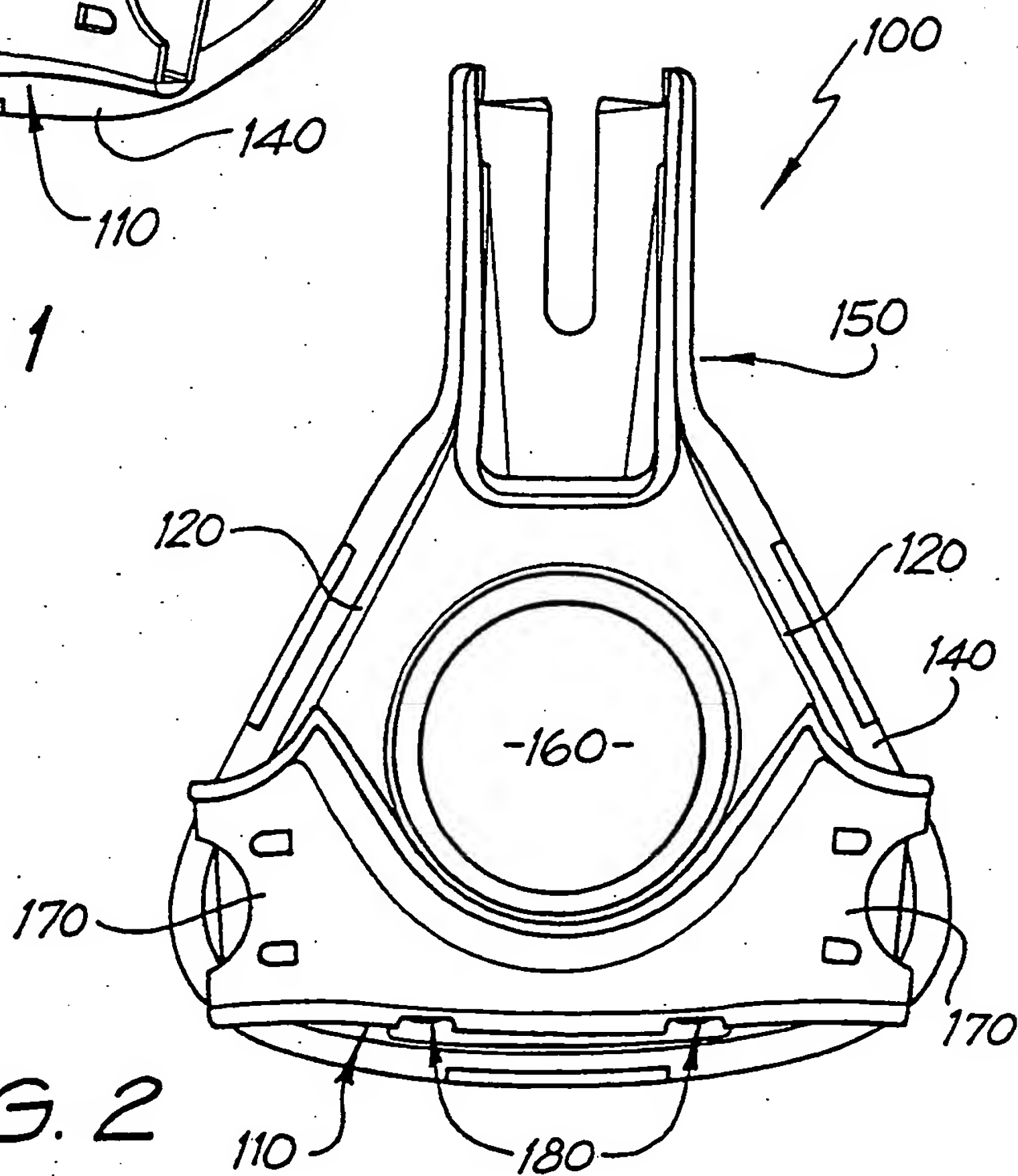


FIG. 2

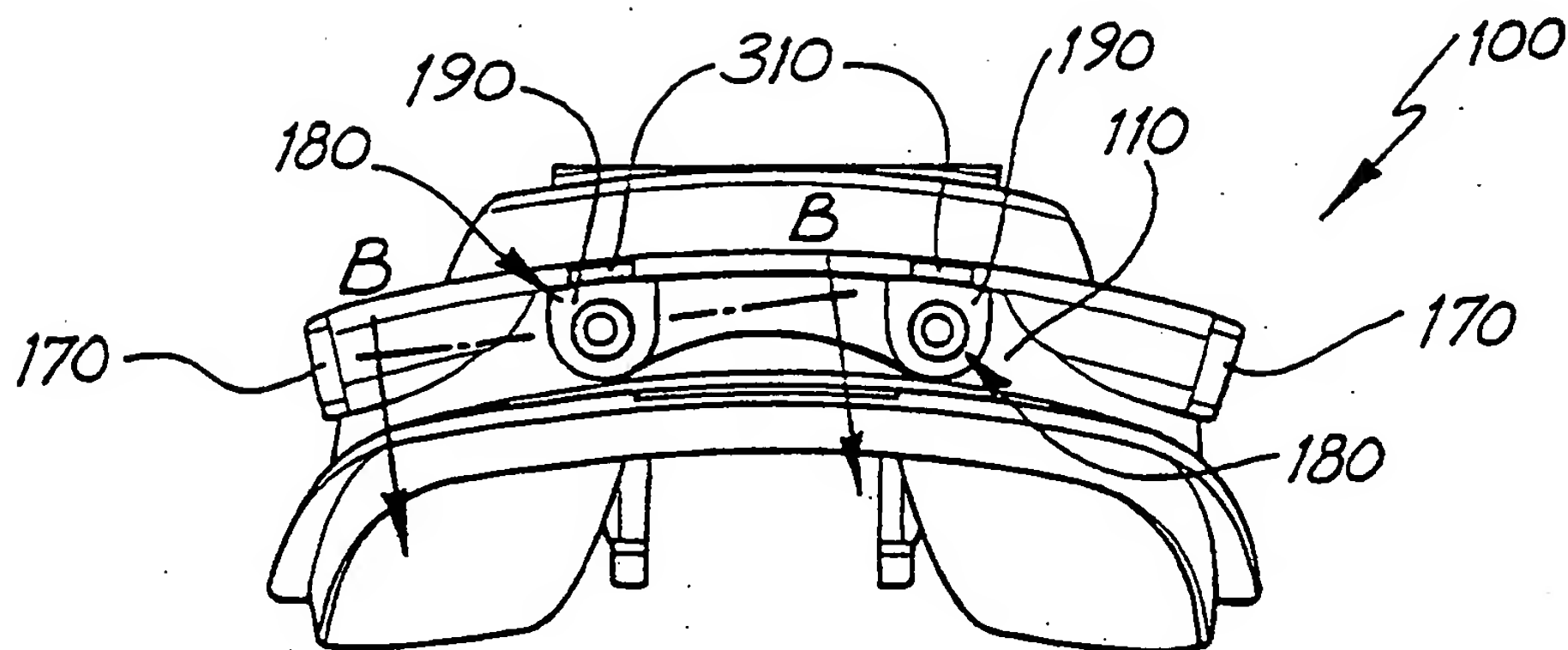


FIG. 3a

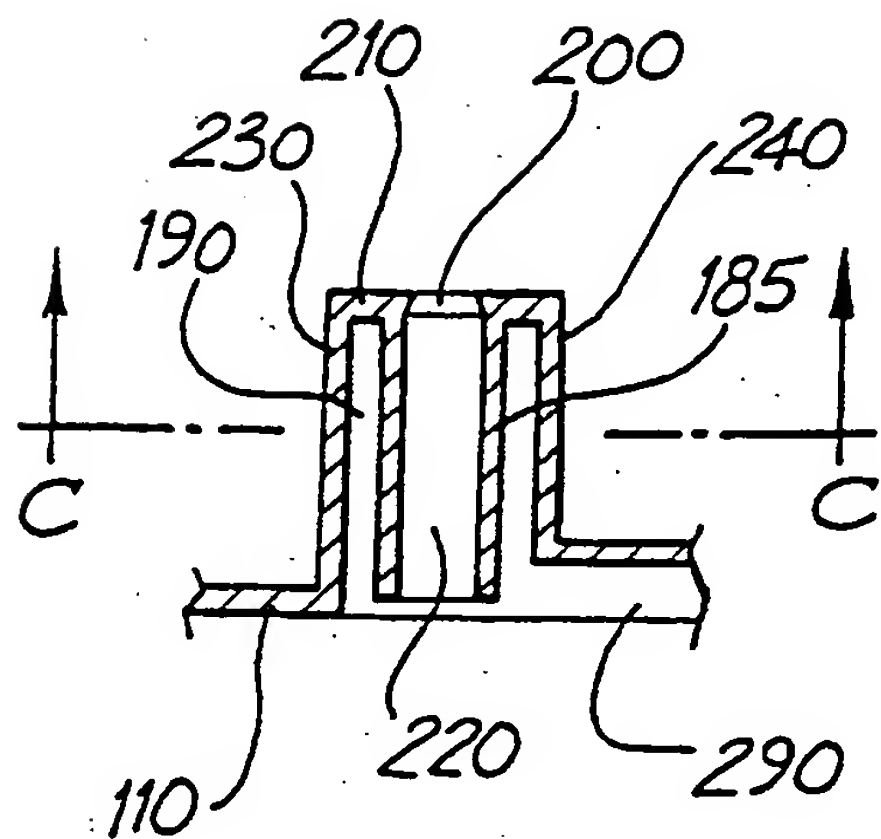


FIG. 3b

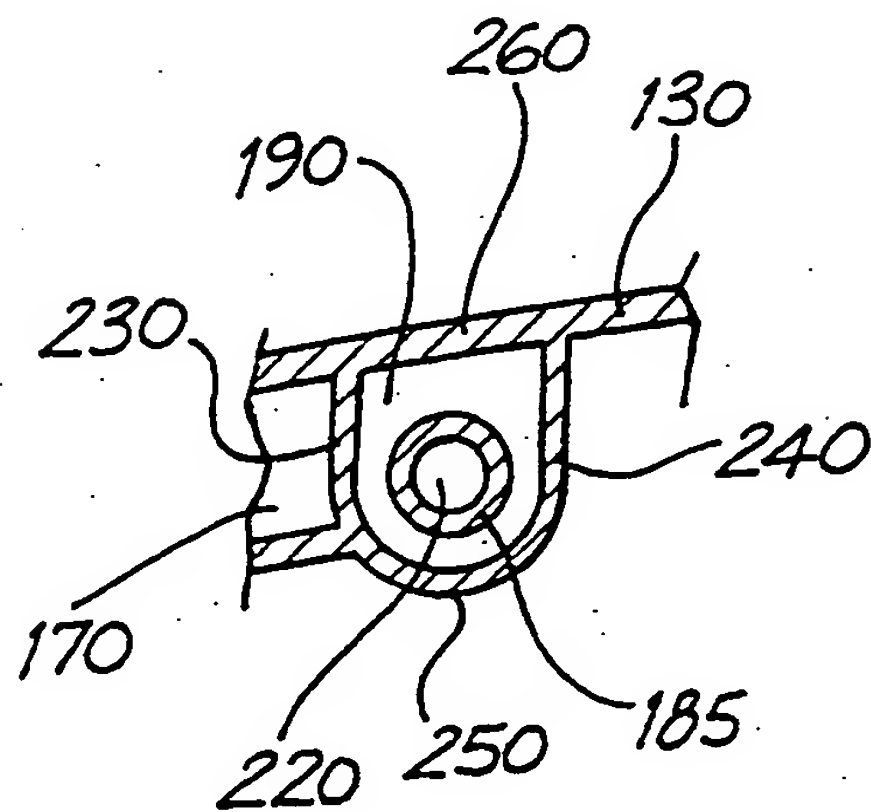


FIG. 3c

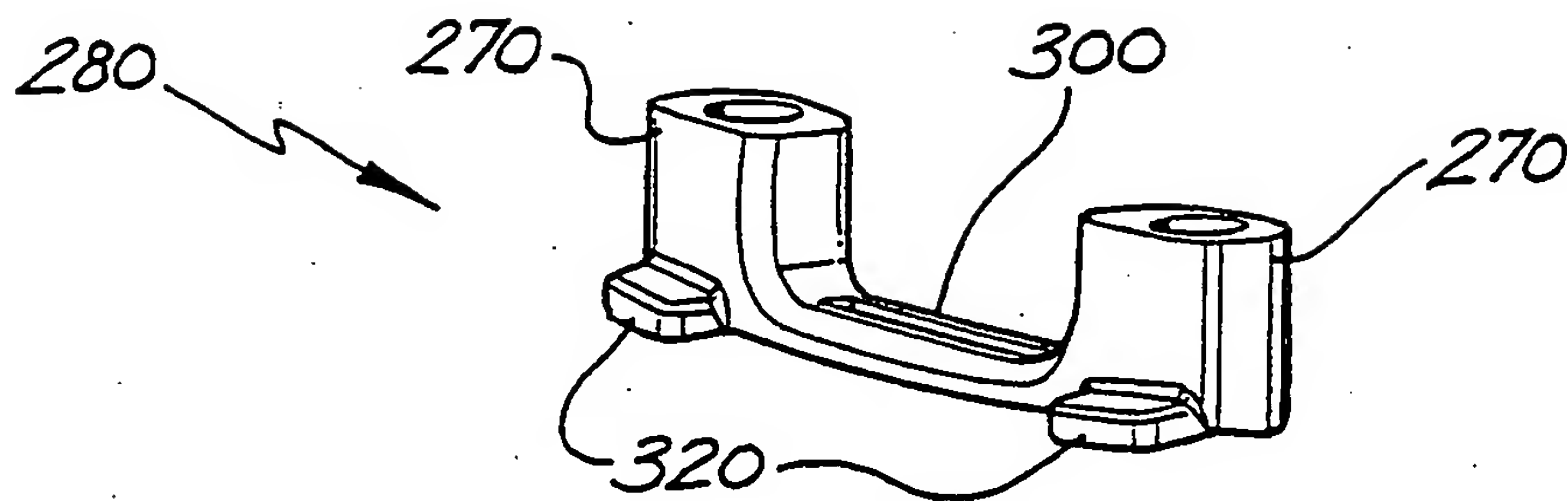


FIG. 4a

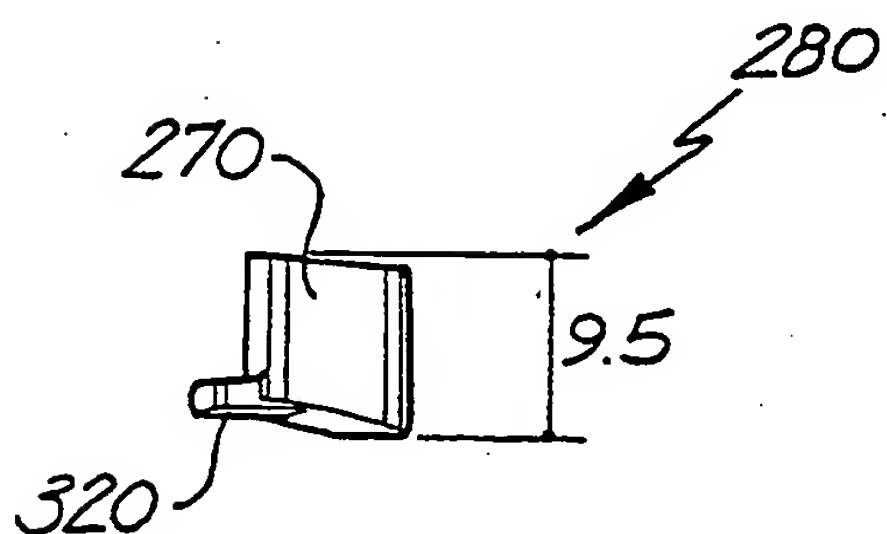


FIG. 4b

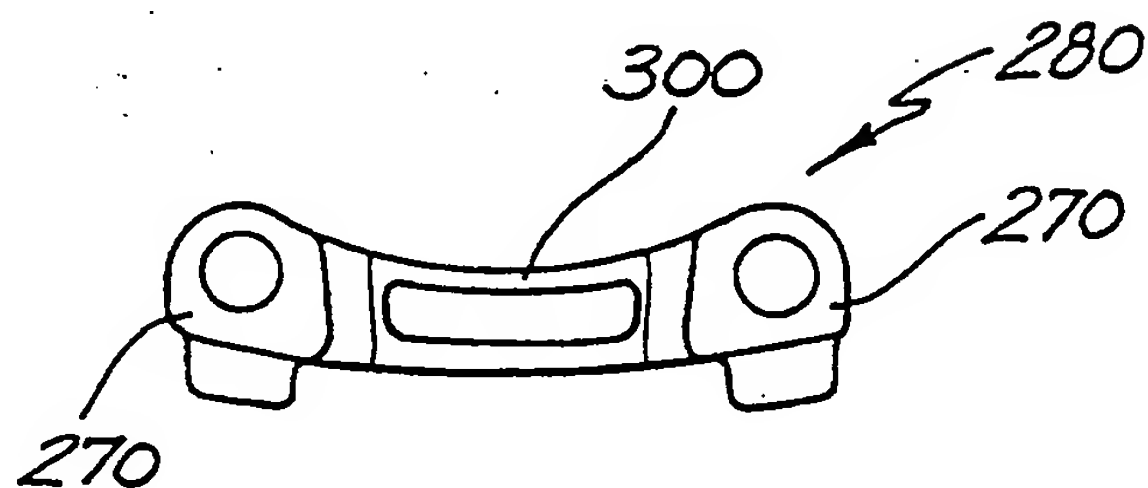


FIG. 4c

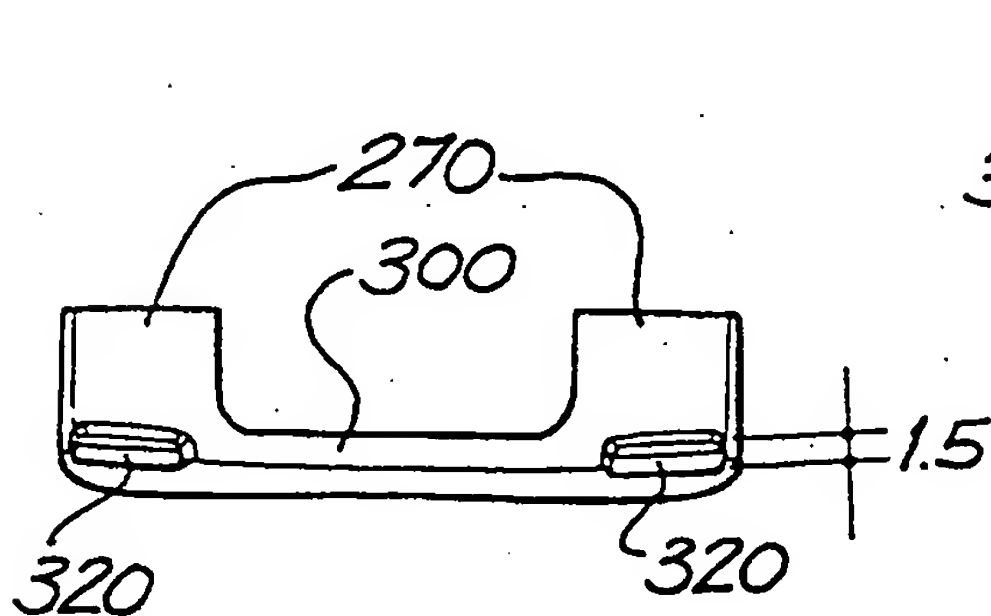


FIG. 4d

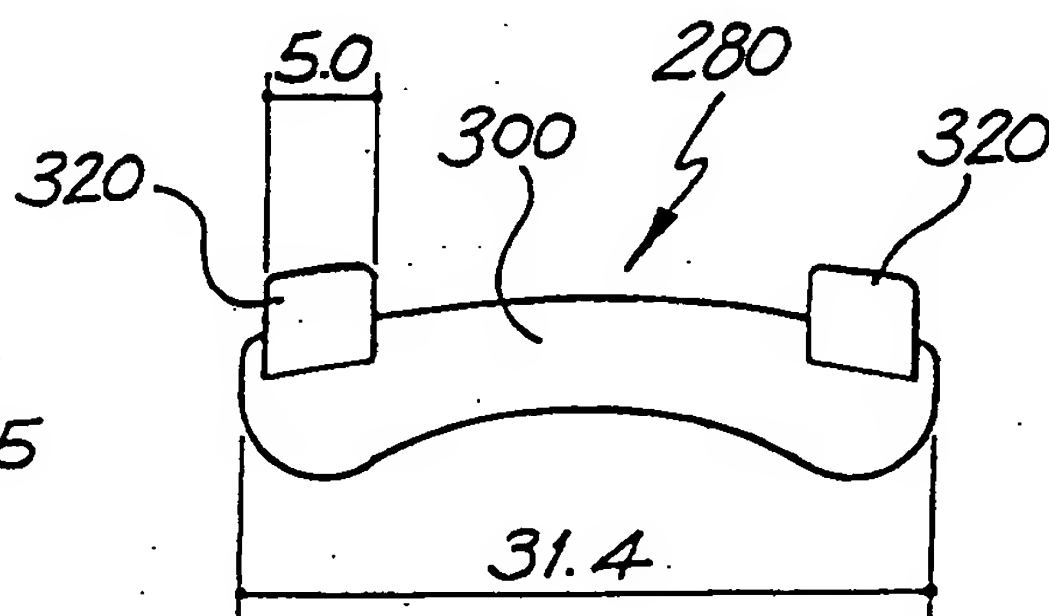


FIG. 4e

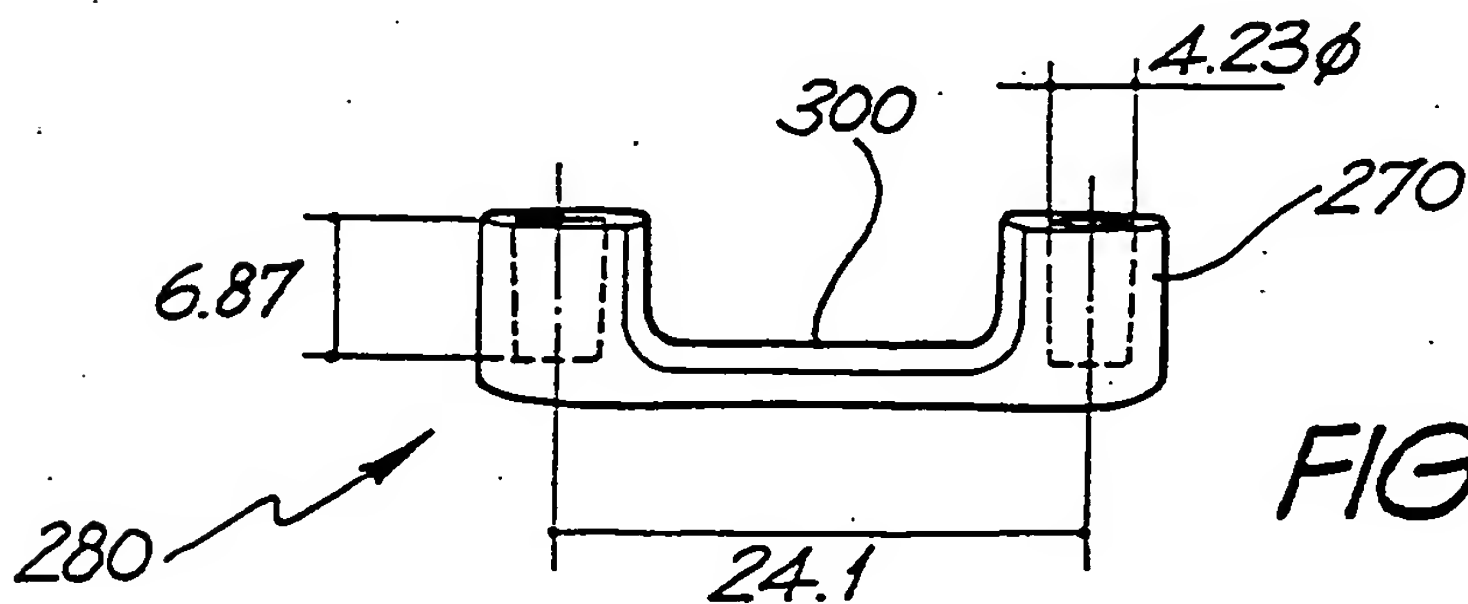


FIG. 4f

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU00/00677

A. CLASSIFICATION OF SUBJECT MATTER												
Int. Cl. ⁷ : A61M 16/06												
According to International Patent Classification (IPC) or to both national classification and IPC												
B. FIELDS SEARCHED												
Minimum documentation searched (classification system followed by classification symbols) A61M 16/- A62B 18/-												
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched												
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) WPAT												
C. DOCUMENTS CONSIDERED TO BE RELEVANT												
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.										
P,X	US 5918598 A (BELFER et al.) 6 July 1999 Column 6 lines 23 to 42	1-6,11-18,23										
X	FR 2766723 A (TI FRANCE SA) 5 February 1999 Figure 1	1-6,11-18,23										
X	GB 649689 A (COLLISON) 31 January 1951 Page 2 lines 5 to 75	1-6,11-18,23										
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C <input checked="" type="checkbox"/> See patent family annex												
<p>* Special categories of cited documents:</p> <table border="0"> <tr> <td>"A" document defining the general state of the art which is not considered to be of particular relevance</td> <td>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</td> </tr> <tr> <td>"E" earlier application or patent but published on or after the international filing date</td> <td>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</td> </tr> <tr> <td>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</td> <td>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</td> </tr> <tr> <td>"O" document referring to an oral disclosure, use, exhibition or other means</td> <td>"&" document member of the same patent family</td> </tr> <tr> <td>"P" document published prior to the international filing date but later than the priority date claimed</td> <td></td> </tr> </table>			"A" document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention	"E" earlier application or patent but published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone	"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art	"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family	"P" document published prior to the international filing date but later than the priority date claimed	
"A" document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention											
"E" earlier application or patent but published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone											
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art											
"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family											
"P" document published prior to the international filing date but later than the priority date claimed												
Date of the actual completion of the international search 18 July 2000		Date of mailing of the international search report - 8 AUG 2000										
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929		Authorized officer <i>D. Melhuish</i> DAVID MELHUIISH Telephone No : (02) 6283 2426										

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU00/00677

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5233978 A (CALLAWAY) 10 August 1993 Column 3 line 40 to column 4 line 10	1,12-16
A	US 4231363 A (GRIMES) 4 November 1980 Figure 1	
A	US 5724965 A (HANDKE et al.) 10 March 1998 Column 4 lines 41 to 46, figure 6	

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/AU00/00677

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report	Patent Family Member
US 5918598	
FR 2766723	
GB 649689	
US 5233978	
US 4231363	
US 5724965	AU 54598/96 AU 89312/98 CA 2177524 EP 747078 JP 9010311
	END OF ANNEX